Attachment I: 510(k) Summary of Safety and Effectiveness

K954957 MAY -7 1996

General Information

Device Generic Name: Defibrillator with arrhythmia detector

Device Trade Name: Shock Advisory Option for CodeMaster

Legally marketed predicate device: Physio Control Likfepak 9 and 9A with Shock Advisory capaility

Applicant:

Hewlett-Packard
Diagnostic Cardiology Division
1700 South Baker Street
McMinnville, Oregon 97128

Indications for Use:

The Shock Advisory Option for CodeMaster defibrillators is intended for use by medical personnel who have completed training and certification requirements applicable to the use of a semi-automatic defibrillator and under a physician approved protocol. It is indicated for use on victims of cardiac arrest where there is apparent lack of circulation as indicated by unconsciousness, absence of breathing, and absence of pulse. The Shock Advisory Option is intended for use in terminating ventricular fibrillation by application of a brief electrical shock to the heart via external adhesive electrodes.

The Shock Advisory Option for CodeMaster is contraindicated for use on patients that are conscious, breathing, pulsatile, or have an implanted pacemaker. The Shock Advisory Option is not intended for pediatric use.

The intended use of the CodeMaster Shock Advisory Option is identical to the intended use of the Physio Control LifePak 9 and 9A defibrillator/monitors used with the Shock Advisory Adapter which received FDA's substantial equivalence determination under K#892005.

CodeMaster defibrillators with Shock Advisory capability may be operated as standard manual defibrillators. Standard CodeMaster defibrillator/monitors are low energy DC-defibrillators (with interchangeable paddles) as described in 21 CFR 870.5300. They are also intended for use by trained medical personnel under a physician approved protocol. Standard CodeMaster defibrillators are intended for use in terminating ventricular fibrillation by application of a brief electrical shock to the heart via external or internal electrodes. They may also be used to treat arrhythmias. This

procedure, called synchronized cardioversion, requires that the defibrillator discharge occur on the ECG R wave in order to avoid induc ng ventricular fibrillation.

The M1722A/B and the M2475B are also intended for external, non-demand or demand pacing if the patient is in a life-threatening asystole, profound bradycardia or any other condition in which the clinician determines that pacing must be initiated immediately. The noninvasive pacer is intended for adult or pediatric use. With regards to pediatric pacing, a determination of the suitability of external pacing for any patient must be made by the clinician. Also, the correct rate and current levels for the patient must be determined and set by the physician.

The M1722A/B and the M2475B provide pulse oximetry. The pulse oximeter is an arterial oxygen-saturation and pulse rate measurement capability which augments the ECG monitoring capability of the device. The pulse oximeter produces the numeric for the oxygen saturation value and pulse rate. The pulse oximeter is intended to be used to determine the oxygen saturation of the blood in cases where the patient's oxygenation is of direct concern and to determine the pulse rate.

Device Description:

The CodeMaster Shock Advisory Option is a software modification operating in the M1722A/B, M1723A/B, and M2475B CodeMaster defibrillator/monitors. The hardware components of CodeMaster with Shock Advisory Option are present in the currently marketed predicate devices.

The CodeMaster Shock Advisory Option acquires and analyzes the electrocardiographic rhythm of a victim suspected to be in cardiac arrest and delivers a defibrillation shock upon operator command. This type of defibrillator operation is generally referred to as semi-automatic external defibrillation.

To use the CodeMaster Shock Advisory Option the operator must first attach adhesive electrode pads. Two disposable adhesive electrodes are used to receive ECG signals and to deliver defibrillation shocks. The electrodes are attached to the patient in the transthoriac position and connected to the device through a detachable cable. ECG rhythm analysis is initiated by the operator after verifying that the patient is unconscious, pulseless and not breathing. The shock advisory algorithm analyzes the electrical activity of the heart and determines if a shockable rhythm is present. If a shockable rhythm is present the defibrillator is automatically charged and a message is displayed on the CRT indicating that a shock is advised. The defibrillation shock is delivered when the operator depresses the discharge buttons on the defibrillator. The operator may repeat the analysis/defibrillation cycle by pressing the Analyze button to start a new analysis period.

The standard semi-automatic external defibrillator operation of the CodeMaster Shock Advisory Option follows the American Heart Association guidelines using 200 joules for

the first two shocks, followed by 360 joules for the third shock. An alternative 200J, 300J, 360J energy sequence can be selected using setup mode.

The front panel of the predicate defibrillator device has been modified to enable an additional switch position already present on the energy select switch of the CodeMaster defibrillators to activate the shock advisory capability and a button to initiate analysis.

The CodeMaster Advisory Event Summary record contains information about the resuscitation attempt. ECG strips are automatically recorded for some events and the operator my record other events by pressing the MARK button. Advisory Event Summary information may be reviewed after the device has been turned off. The information in memory is cleared when the unit is powered on and a new advisory recording occurs. Advisory Event Summary is not present on the CodeMaster XL (Model M1723A/B).

At any time, if the energy select switch is moved from Advisory to a manual energy setting, the defibrillators will operate in standard manual defibrillator mode. In the manual mode the operator controls defibrillator charging, energy selection, and defibrillation delivery. The Shock Advisory capability is not operational in the manual defibrillator mode.

CodeMaster defibrillator/monitor features include recorder, optional noninvasive pacer, and optional pulse oximeter. They can be used with adult/pediatric external paddles, anterior/posterior paddles, external pads, or internal paddles. Energy selection ranges from 2 joules to 360 joules based on a 50 ohm load. Internal paddles are limited to 50 joules output. CodeMaster defibrillators will charge to the selected energy level in five seconds and will disarm itself if not discharged within 60 seconds. They may be used to defibrillate, cardiovert, pace, monitor ECG, and monitor oxygen saturation. The M1722A/B and M2475B provide an Event Summary of data in a format that facilitates code documentation.

Marketing History

The Shock Advisory Option for CodeMaster is not currently sold in the U.S. or foreign markets.

Adverse Effects of the Device on Health

Patients requiring treatment for ventricular fibrillation will die if a defibrillator is not used to restore an acceptable rhythm. If this device is used incorrectly, or fails to operate the result will also most likely be death or injury of the patient. This device provides ECG waveform information as well as high and low heart rate alarms.